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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/685,744	10/14/2003	Robert F. Rioux	267/296 (01-402)	6134

7590 03/15/2006

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EXAMINER	
TOY, ALEX B	

ART UNIT	PAPER NUMBER
3739	

DATE MAILED: 03/15/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/685,744	RIOUX ET AL.	
	Examiner	Art Unit	
	Alex B. Toy	3739	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *17 February 2006*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-16* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-16* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *14 October 2003* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Response to Amendment

This Office Action is in response to applicant's amendment filed on February 17, 2006. The examiner maintains all prior rejections.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1-4 and 6-15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Edwards et al (U.S. Pat. No. 6,071,280) in view of VanTassel et al. (U.S. Pat. No. 6,241,710 B1).

Regarding claim 1, Edwards et al. disclose an apparatus for delivering electrical energy to tissue within a patient, comprising:

a tubular member 12 comprising a proximal end 14, a distal end 16 having a size for insertion into a body of a patient, and a lumen extending from the distal end towards the proximal end (Fig. 2); and

a needle 20 comprising a distal portion extending at least partially from the lumen and terminating in a tissue-piercing distal tip, the distal portion comprising an electrically conductive material, thereby providing an electrode through which electrolytic fluid may flow for delivering electrical energy to tissue surrounding the distal portion (col. 9, ln. 64-66, col. 10, ln. 12-16, and Figs. 13-15).

The claim differs from Edwards et al. in calling for the distal portion of the needle tip to comprise a porous material. VanTassel et al., however, teach a needle 2, wherein the distal portion comprises porous sintered stainless steel to allow fluid to flow through pores in the walls of the needle shaft (col. 5, ln. 21-29, col. 5, ln. 41-45, and Fig. 1). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have made the distal portion of the needle of Edwards et al. from porous sintered stainless steel in view of the teaching of VanTassel et al. as an obvious alternate way of allowing fluid to flow through the walls of the needle shaft that is known in the art.

Regarding claim 2, Edwards et al. disclose the apparatus of claim 1 in view of VanTassel et al. Edwards et al. also disclose that the distal portion of the needle comprises stainless steel (col. 8, ln. 29-30). The claim differs from Edwards et al. in calling for the distal portion to comprise specifically sintered stainless steel. VanTassel et al., however, teach a needle 2, wherein the distal portion comprises sintered stainless

steel to allow fluid to flow through pores in the walls of the needle shaft (col. 5, ln. 21-29, col. 5, ln. 41-45, and Fig. 1). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have made the distal portion of the needle of Edwards et al. in view of VanTassel et al. from sintered stainless steel also in view of the teaching of VanTassel et al. as an obvious alternate way of allowing fluid to flow through the walls of the needle shaft that is known in the art.

Regarding claim 3, Edwards et al. disclose the apparatus of claim 1 in view of VanTassel et al. In addition, Edwards et al. disclose a needle, wherein the needle comprises a needle lumen extending from a proximal end of the needle to the distal portion. Since electrolytic fluid is introduced to the ablation site through an initial connection to a fluid source at the proximal handle 10, the needle 20 must inherently comprise a needle lumen extending from a proximal end of the needle to the distal portion (col. 10, ln. 12-16 and Figs. 1 and 14).

Regarding claim 4, Edwards et al. disclose the apparatus of claims 1 and 3 in view of VanTassel et al. In addition, Edwards et al. disclose the apparatus further comprising a source of electrolytic fluid coupled to the needle lumen for delivering electrolytic fluid to the distal portion of the needle. Since electrolytic fluid is introduced to the ablation site through needle 20, one of the tubes attached to the handle 10 in Fig. 1 must inherently couple a source of electrolytic fluid to the needle lumen for delivering electrolytic fluid to the distal portion of the needle (col. 10, ln. 12-16 and Figs. 1 and 14).

Regarding claim 6, Edwards et al. disclose the apparatus of claim 1 in view of VanTassel et al. In addition, Edwards et al. disclose a needle 20, wherein the needle is

movable relative to the tubular member 12 for at least one of retracting the distal portion into the tubular member and deploying the distal portion from the tubular member (col. 6, ln. 16-30, col. 9, ln. 55-65, and Figs. 11-15).

Regarding claim 7, Edwards et al. disclose the apparatus of claim 1 in view of VanTassel et al. In addition, Edwards et al. disclose a tubular member 12, wherein the tubular member comprises an electrically insulating sleeve 28 (col. 9, ln. 7-9 and Fig. 13.

Regarding claim 8, Edwards et al. disclose the apparatus of claim 1 in view of VanTassel et al. In addition, Edwards et al. disclose a plurality of needles 20 extendable from the lumen beyond the distal end of the tubular member 12, each needle comprising a distal tip for penetrating tissue (Figs. 11-13).

Regarding claim 9, Edwards et al. disclose the apparatus of claims 1 and 8 in view of VanTassel et al. Edwards et al. disclose that each of the plurality of needles comprises a distal portion comprising an electrically conductive and porous material in view of VanTassel et al. because if it is obvious to modify one needle, it is obvious to modify the plurality of needles. (See the preceding rejection of claim 1.) In addition, Edwards et al. disclose an array of porous electrodes 20 through which electrolytic fluid may flow for delivering electrical energy to tissue adjacent the distal portions of the array of electrodes (col. 10, ln. 12-16 and Figs. 13-15).

Regarding claim 10, Edwards et al. disclose an apparatus for delivering electrical energy to tissue within a patient, comprising:

a tubular member 12 comprising a proximal end 14, a distal end 16 having a size for insertion into a body of a patient, and a lumen extending from the-distal end towards the proximal end of the tubular member (Fig. 2); and

an array of needles 20 extendable from the lumen beyond the distal end of the tubular member, each needle comprising a distal tip for penetrating tissue, at least one needle comprising a distal portion comprising an electrically conductive material, thereby providing a porous electrode through which electrolytic fluid may flow for delivering electrical energy to tissue adjacent the distal portion. (col. 9, ln. 64-66, col. 10, ln. 12-16, and Figs. 11-15).

The claim differs from Edwards et al. in calling for the distal portion of the needle tip to comprise a porous material. VanTassel et al., however, teach a needle 2, wherein the distal portion comprises porous sintered stainless steel to allow fluid to flow through pores in the walls of the needle shaft (col. 5, ln. 21-29, col. 5, ln. 41-45, and Fig. 1). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have made the distal portion of the needle of Edwards et al. from porous sintered stainless steel in view of the teaching of VanTassel et al. as an obvious alternate way of allowing fluid to flow through the walls of the needle shaft that is known in the art.

Regarding claim 11, Edwards et al. disclose the apparatus of claim 10 in view of VanTassel et al. In addition, Edwards et al. disclose needles 20, wherein the needles are movable from a retracted configuration within the lumen to an extended

configuration wherein distal portions of the needles extend beyond the distal end of the tubular member 12 (col. 6, ln. 16-30, col. 9, ln. 55-65, and Figs. 11-15).

Regarding claim 12, Edwards et al. disclose the apparatus of claims 10 and 11 in view of VanTassel et al. In addition, Edwards et al. disclose a plurality of needles 20, wherein the plurality of the needles have distal tips that extend different axial and radial distances from one another in the extended configuration (col. 7, ln. 34-54).

Regarding claim 13, Edwards et al. disclose the apparatus of claims 10 and 11 in view of VanTassel et al. In addition, Edwards et al. disclose that a distal portion of a plurality of the needles comprises an electrically conductive material defining an electrode (col. 6, ln. 20-21 and Figs. 14-15). The distal portion comprises a porous material in view of VanTessel et al. (See the preceding rejection of claim 10.)

Regarding claim 14, Edwards et al. disclose the apparatus of claim 10 in view of VanTassel et al. In addition, Edwards et al. disclose a source of conductive fluid connected to the infusion lumen of each needle comprising an infusion lumen. Since conductive fluid is introduced to the ablation site through needles 20, one of the tubes attached to the handle 10 in Fig. 1 must inherently connect a source of conductive fluid to the infusion lumens of each needle comprising an infusion lumen (col. 10, ln. 12-16 and Figs. 1 and 14).

Regarding claim 15, Edwards et al. disclose the apparatus of claims 10 and 14 in view of VanTassel et al. In addition, Edwards et al. disclose a hub proximal to the distal end of the tubular member, the hub comprising a port connected to the source of

conductive fluid, the hub communicating with each infusion lumen for delivering conductive fluid from the source of conductive fluid to each porous electrode. Since there are two lines connected to the handle 10 shown in Fig. 1, one must be connected to the RF generator, and the other must be connected to the source of conductive fluid. Therefore, since there is only one line that connects the source of conductive fluid to each of the electrodes, there inherently must be a hub as claimed to connect the source of conductive fluid to each infusion lumen for delivering conductive fluid to each porous electrode.

Claim 5 is rejected under 35 U.S.C. 103(a) as being unpatentable over Edwards et al. ('280) in view of VanTassel et al. ('710) and further in view of Rangaswamy (U.S. Pat. No. 4,512,768).

Regarding claim 5, Edwards et al. disclose the apparatus of claim 1, wherein the distal portion of the needle comprises a porous material in view of VanTassel et al. The claim differs from Edwards et al. in calling for the entire needle to comprise porous material. Rangaswamy, however, teaches a needle 42 with pores 44 around and along its entire length to provide for uniform fluid infusion along the entire length of the inserted needle and not just at the end (col. 2, ln. 65 – col. 3, ln. 5 and Fig. 1). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have made the entire needle of Edwards et al. in view of VanTassel et al. from the porous sintered stainless steel of VanTassel et al. further in

view of the teaching of Rangaswamy to provide for uniform infusion of the electrolytic fluid along the entire length of the inserted needle and not just at the end.

Claim 16 is rejected under 35 U.S.C. 103(a) as being unpatentable over Edwards et al. ('280) in view of VanTassel ('710) and further in view of Kirsch et al. (U.S. Pat. No. 6,503,225 B1).

Regarding claim 16, Edwards et al. disclose the apparatus of claims 10 and 14 in view of VanTassel et al. The claim differs from Edwards et al. in calling for a float valve connected to the source of conductive fluid for removing gases from conductive fluid being delivered from the source of conductive fluid to each porous electrode. Kirsch et al., however, teach a catheter medical device with a float valve 10 with hydrophobic membranes 50 connected at 28 to the source of conductive fluid (such as saline) for removing gases from the fluid being delivered from the source of the fluid to the internal site of treatment in order to prevent injury to the patient due to air embolism (col. 1, ln. 24-37, col. 4, ln. 9-14, col. 7, ln. 1-9, and Figs. 1-6. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have included in the apparatus of Edwards et al. in view of VanTassel et al. a float valve as in claim 16, further in view of the teaching of Kirsch et al. to prevent injury to the patient due to air embolism during treatment.

Response to Arguments

Applicant's arguments filed on February 17, 2006 have been fully considered but they are not persuasive.

In response to applicant's argument that VanTassel is nonanalogous art, it has been held that a prior art reference must either be in the field of applicant's endeavor or, if not, then be reasonably pertinent to the particular problem with which the applicant was concerned, in order to be relied upon as a basis for rejection of the claimed invention. See *In re Oetiker*, 977 F.2d 1443, 24 USPQ2d 1443 (Fed. Cir. 1992). In this case, VanTassel, Edwards, and applicant are all concerned with delivering fluid from a needle into tissue.

In response to applicant's argument that there is no suggestion to combine the references, the examiner recognizes that obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. See *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988)and *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992). In this case, using the knowledge generally available to one of ordinary skill in the art, it would have been obvious to modify Edwards in view of VanTassel because both references use pores in a needle shaft to deliver fluid into tissue.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Alex B. Toy whose telephone number is (571) 272-1953. The examiner can normally be reached on Monday through Friday, 8:00 AM to 4:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Linda C.M. Dvorak can be reached on (571) 272-4764. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

AT AT
3/6/06

MICHAEL PEFFLEY
PRIMARY EXAMINER